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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,437

09/29/2005

Katsuya Togawa

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07/22/2009

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EXAMINER

GERIDO, DWAN A

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,437	<b>Applicant(s)</b> TOGAWA ET AL.	
	<b>Examiner</b> Dwan A. Gerido, Ph.D.	<b>Art Unit</b> 1797	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the inner and outer surfaces of the sample collection part, and the flow channel opposite the through hole must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Objections***

2. Claims 5 and 6 are objected to because of the following informalities: claims 5 and 6 are directed to a method, but are dependent on claim 4 which is directed to an apparatus.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 1, 2, and 7-11 are rejected under 35 U.S.C. 102(a) as being anticipated by Stevens et al., (US 2004/0013575).

5. For claims 1 and 2, Stevens et al., teach a method for filtering a sample comprising a container having an internal chamber (sample collection part, paragraph 0052, figure 1 #14), a plug member to seal the opening of the chamber (paragraph 0052, figure 1 #22), a filter for filtering the sample (paragraphs 0052, 0057, figure 1 #13), and a sample storage part for storing a sample (figure 1 area below filter 13 generally denoted as #12). The steps of collecting a sample using a vacuum blood collection needle, and filtering by a pressure gradient are being read as inherent features in the teachings of Stevens et al. For example, examination of figure 1 of Stevens et al., reveals a hollow collection needle that generates communication to the exterior (paragraph 0054, figure 1 #26) thereby generating a pressure difference between the collection and storage parts.

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6. For claims 7-9, Stevens et al., teach a container comprising an internal chamber (sample collection part, paragraph 0052, figure 1 #14), a plug (paragraph 0052, figure 1 #22), a filter (paragraphs 0052, 0057, figure 1#13), a sample storage part (figure 1 area below filter 13 generally denoted as #12). Stevens et al., teach the container being sterile and holding sterile products which reads on the claimed device being hermetically connected (paragraphs 0039, 0052, 0054). Stevens et al., also teach the plug having a through hole that can be pierced and resealed which reads on the claimed sealing member on the outer surface of the plug member (paragraph 0054).

7. For claim 10, Stevens et al., teach a container comprising a sample collection part, plug, filter, and sample storage part as detailed in the preceding paragraph. Additionally, Stevens et al., teach an open hole formed in a part of the inner surface of the collection part in contact with the plug (figure 1, top hole of pierced plug), and a flow channel (figure 1, vertical channel of pierced plug) that allows communication between the through hole and the interior of the sample collection part.

8. For claim 11, Stevens et al., teach a container comprising a sample collection part, plug, filter, and sample storage part as detailed in paragraph 6. Additionally, Stevens et al., teach the plug having two through holes (figure 1, top and bottom holes of pierced plug), and a flow channel (figure 1, vertical channel of pierced plug). The arrangement of the through holes, and the flow channel in the device of Stevens et al., are such that when the plug member is drawn from the collection part one end of the channel is opposite the through hole (figure 1, top portion of channel in pierced plug) while the other end is open to the collection part (figure 1, bottom portion of channel in pierced plug).

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***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens et al (US 2004/0013575) in view of Brown et al., (US 3,837,376).

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13. With regards to claim 3, Stevens et al., do not teach a needle having a communication groove on its outer surface and extending from the needlepoint to an opposite end to the needlepoint.

Brown et al., teach a blood serum collection tube comprising a needle having openings (communication groove) on its outer surface (column 2 lines 56-62, figures 1-3 #'s 5, 6). Brown et al., teach that it is advantageous to have the openings on the outer surface of the needle as a means of providing communication between the inside of the tube and the atmosphere.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Stevens et al., in view of Brown et al., to utilize a communication groove in order to provide communication between the inside of the container and the atmosphere as taught by Brown et al. It is noted that reference to Brown et al., does not explicitly teach the opening (communication groove) extending from a needlepoint to an opposite end of the needlepoint.

This limitation is being read as a change in size and is deemed obvious in view of the teachings of Brown. The openings of Brown et al., and the communication groove of the instant application function in the same manner, namely to generate communication between the interior of the container and the exterior environment thus the only difference between the prior art and the claimed limitation is the relative size (length) of the opening. The MPEP states that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Brown et al., wherein the communication groove extends from

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the needlepoint to an end opposite the needlepoint as changes in size require only routine skill in the art.

14. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al., (US 3,837,376) in view of Altman et al., (US 2002/0177772).

15. With regards to claims 4-6 Brown et al., teach a jig for collecting a sample comprising a communication needle having a flow channel (hollow portion of needle) extending from the needlepoint to the opposite end of the needle (column 2 lines 52-56, column 3 lines 11-17), a gripping portion attached to the end of the needle (column 2 lines 62-67, figures 1-3 #21), and a skirt portion extending in an axial direction from the gripping portion (figures 1-3 #15). Brown et al., also teach the needle having two openings ((column 2 lines 56-62, figures 1-3 #'s 5, 6) which are being read on the claimed communication groove. It is noted that reference to Brown et al., does not explicitly teach the opening (communication groove) extending from a needlepoint to an opposite end of the needlepoint. This limitation is being read as a change in size and is deemed obvious in view of the teachings of Brown. The openings of Brown et al., and the communication groove of the instant application function in the same manner, namely to generate communication between the interior of the container and the exterior environment thus the only difference between the prior art and the claimed limitation is the relative size (length) of the opening. The MPEP states that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Brown et



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al., wherein the communication groove extends from the needlepoint to an end opposite the needlepoint as changes in size require only routine skill in the art. Brown et al., do not teach the needlepoint having a vane.

Altman et al., teach a drug delivery catheter comprising a needle wherein the needle has barbs (vanes) located at the needlepoint (paragraph 0083, figure 4 #466). Altman et al., teach that it is advantageous to utilize a barb as a means of holding the needle in place. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Brown et al., in view of Altman et al., to form a vane at the needlepoint in order to prevent random movement of the needle as taught by Altman et al.

### ***Response to Arguments***

16. Applicant's arguments with respect to claims 1-11 have been considered but are moot in view of the new ground(s) of rejection.

17. Applicant has argued that the combination of references applied in the previous Office action do not teach the limitations of the instant claims. The claims as presented in applicant's response dated March 3, 2009 are now under new grounds of rejection thereby rendering applicant's arguments moot. The examiner notes that in the above Office action, the drawings have been objected to for failing to show features specified in the claims. Additionally, claims 5 and 6 have been objected to as claims 5 and 6 are method claims that are dependent on an apparatus. It is the examiners position that the art applied in the above Office action teaches the limitations of the claims as presented in applicant's response of March 3, 2009.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwan A. Gerido, Ph.D. whose telephone number is (571)270-3714. The examiner can normally be reached on Monday - Friday, 9:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lyle A Alexander/  
Primary Examiner, Art Unit 1797

DAG